Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2012.

Through an audit performed on behalf of

Robert Schindele GesmbH
Kicking 18, 3122 Gansbach, Austria

it could be demonstrated that a quality management system

according to **DIN EN ISO 13485:2012**
"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the **manufacturing and distribution of medical devices based on stone powder for internal use**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number	Registered under	Valid until
643-16-83	Z/17/04046E	March 31st, 2019

Aachen, 05.04.2017

Certification Body